

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of: \  
Pandian et al. \

Filed: Herewith \

For: METHODS AND KITS FOR DETECTING ITA IN A \

BIOLOGICAL SAMPLE \

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

**INFORMATION DISCLOSURE STATEMENT**

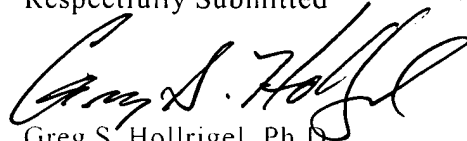
Sir:

In accordance with 37 C.F.R. 1.56 and 1.97, Applicants wish to call the attention of the Examiner to the references that are listed on the attached PTO form 1449. No copies of the references are being provided per 37 C.F.R. 1.98(d), since they were cited by or submitted to the Office in parent application U.S. Serial Number 09/918,299.

Applicant respectfully requests that the cited references be listed on the face of any patent issuing from this application.

These citations do not constitute an admission that the references are relevant or material to the claims, but rather only constitute the closest art of which Applicants are presently aware.

Respectfully Submitted



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November 18, 2003  
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949-450-1750

Form PTO-1449			Docket Number (Optional) <b>A-1789div</b>		Application Number		
<b>INFORMATION DISCLOSURE CITATION IN AN APPLICATION</b> (Use several sheets if necessary)			Applicant <b>Pandian et al.</b>		Group Art Unit		
			Filing Date <b>herewith</b>				
<b>U. S. PATENT DOCUMENTS</b>							
EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	RULING DATE IF APPROPRIATE	
	4,946,958	8/1990	Campbell et al.				
	5,356,817	10/2002	Cole et al.				
	5,506,150	4/09/96	Canick et al.				
	5,660,990	08/1997	Rao et al.				
	6,127,186	10/03/00	Pandian				
	6,352,862	03/2002	Davis et al.				
<b>FOREIGN PATENT DOCUMENTS</b>							
	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
						YES	NO
	98/10282	3/12/1998	WO				No
	99/41584	8/19/1999	WO				No
	99/56132	11/04/1999	WO				No
	00/42428	7/20/2000	WO				No
	00/70094	11/23/2000	WO				No
<b>OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)</b>							
	Bahado-Singh R et al., "A high-sensitivity alternative to 'routine' genetic amniocentesis: multiple urinary analytes, nuchal thickness, and age." Am J Obstet Gynecol 1999 Jan;180(1 Pt 1): 169-73.						
	Cole LA et al., "Urinary screening tests for fetal Down syndrome: I. Fresh $\beta$ -core fragment." Prenat Diagn. 1999 Apr, 19(4): 340-50.						
	Bahado-Singh RO et al., "New triple screen test for Down syndrome: combined urine analytes and serum AFP." J Matern Fetal Med. 1998 May-June;7(3):111-4.						
	Kellner LH et al., "Levels of urinary beta-core fragment, total oestriol, and the ratio of the two in second-trimester screening for Down syndrome." Prenat Diagn. 1997 Dec;17(12):1135-41						
	Cole La et al., "Combining beta-core fragment and total oestriol measurements to test for Down syndrome ..." Prenat Diagn. 1997 Dec;17(12):1125-33.						
	Cuckle HS et al., "Urinary multiple marker screening for Down's syndrome." Prenat Diagn. 1995 Aug;15(8):745-51.						
	Bahado-Singh RO et al., "Comparison of urinary hyperglycosylated human chorionic gonadotropin concentration with the serum triple screen for Down syndrome detection in high-risk pregnancies." Am J Obstet Gynecol. 2000 Nov;183(5):1114-8						
	Cole LA et al., "Urinary screening tests for fetal Down syndrome: II. Hyperglycosylated hCG." Prenat Diagn. 1999 Apr; 19(4):351-9						
	Cole LA et al., "Hyperglycosylated hCG, a potential alternative to hCG in Down syndrome screening." Prenat Diagn. 1998 Sep; 18(9):926-33.						
	Hsu JJ et al., "Urine free beta-hCG and total estriol for Down syndrome screening during the second trimester in an Asian population." Obstet Gynecol 1999 Jul;94(1):107-11.						
<b>EXAMINER</b>			<b>DATE CONSIDERED</b>				
EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP § 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to the applicant.							

Form PTO-1449

# **INFORMATION DISCLOSURE CITATION IN AN APPLICATION**

(Use several sheets if necessary)

Docket Number (Optional) **A-1789div**

Application Number

Applicant **Pandian et al.**Filing Date **herewith**

Group Art Unit

## **U. S. PATENT DOCUMENTS**

EXAMINER INITIAL	DOCUMENT NUMBER	DATE	NAME	CLASS	SUBCLASS	RULING DATE IF APPROPRIATE

## **FOREIGN PATENT DOCUMENTS**

DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUBCLASS	TRANSLATION	
					YES	NO

## **OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)**

	Spencer K et al., "First-trimester urine free beta hCG, beta core, and total oestriol in pregnancies affected by Down's syndrome: implications for first-trimester screening with nuchal translucency and serum free beta hCG." Prenat Diagn 1997 Jun;17(6):525-38.
	Isozaki T et al., "Screening for Down syndrome pregnancy using $\beta$ -core fragment: prospective study." Prenat Diagn 1997 May;17(5):407-13.
	Spencer K et al., "Urine free beta hCG and beta core in pregnancies affected by Down's syndrome." Prenat Diagn 1996 Jul;16(7):605-13
	Krichevsky A et al., "The development of a panel of monoclonal antibodies to human luteinizing hormone and its application to immunological mapping and two-site assays." Endocrine 1994, 2, 551-520
	O'Conner JF et al., Differential Urinary Gonadotrophin Profiles in Early Pregnancy and Early Pregnancy Loss." Prenat Diagn 18: 1232-1240 (1998)
	Unknown "Serum Hyperglycosylated hCG: a Potential Screening Test for Fetal Down Syndrome." Prenat. Diagn. 19:488-490 (1999)
	Cole LA et al., "Hyperglycosylated Human Chorionic Gonadotropin (Invasive Trophoblast Antigen) Immunoassay: A New Basis for Gestational Down Syndrome Screening." Clinical Chemistry 45:12 2109-2119. (1999).
	Abushoufa RA et al, "The development of a sialic acid specific lectin-immunoassay for the measurement of human chorionic gonadotrophin glycoforms in serum and its application in normal and Down's syndrome pregnancies." Clinical Endocrinology (2000) 52, 499-508.
	Birken S. et al., "Development and Characterization of Antibodies to a Nicked and Hyperglycosylated Form of hCG from a Choriocarcinoma Patient." Endocrine, 10:(2) 137-144 April 1999.
	Krichevsky A. et al., "Development, Characterization, and Application of Monoclonal Antibodies to the Native and Synthetic $\beta$ COOH-Terminal Portion of Human Chorionic Gonadotropin (hCG) That Distiguishes between the Native and Desialylated Forms of hCG" Endocrinology 1994 Mar;134(3):1139-45.
	Krichevsky A. et al. "Development and Characterization of a New, Highly Specific Antibody to the Human Chorionic Gonadotropin- $\beta$ Fragment." Endocrinology 1991 Mar;128(3):1255-64.
	"Utility of Commonly Used Commercial Human Chorionic Gonadotropin Immunoassays in the Diagnosis and Management of Trophoblastic Diseases" by Cole et al.; Clinical Chemistry, Feb. 2001, vol. 47, no. 2, pages 308-315

EXAMINER

DATE CONSIDERED

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